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Development of an oscillating/rotating/pulsating toothbrush: The Oral-B ProfessionalCare™ Series

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Summary The Oral-B range of power toothbrushes are based on a clinically proven oscillating/rotating action. This review considers the extensive series of laboratory and clinical studies involved in the development of the Oral-B power toothbrushes with three-dimensional (3D) brush head action (i.e. oscillating/rotating/pulsating), now known as the Oral-B ProfessionalCare™ Series. The unique, highly effective cleaning performance of the 3D action incorporated in the D15 and D17 models is proven in both the laboratory and clinical environments, thereby establishing an evidence-based platform for the development of the most recent ProfessionalCare 7000. In the early development phase, *in-vitro* studies indicated that the additional pulsating action and advancements in filament technology improved approximal penetration, where plaque removal is most difficult. *in-vitro* models provide a useful development tool for the rapid assessment of design modifications, while controlling many factors that confound *in-vivo* studies, but the relevance of their findings needs to be confirmed in the clinical situation by direct improvements in oral health. Results from well-controlled, randomised clinical studies in the development programme have demonstrated the superiority of the D15 and D17 models with 3D action over a manual toothbrush and other power toothbrushes of various actions and designs in the improvement of oral health outcomes such as plaque removal (especially from approximal sites), reduction of gingival inflammation, and control of calculus and stain formation, with no greater potential to cause oral tissue abrasion. Furthermore, user acceptance of the oscillating/rotating/pulsating toothbrush may encourage long-term compliance during normal use.

Evolution of the Oral-B power toothbrush

It is well established that power toothbrushes have the potential to overcome many of the difficulties associated with manual toothbrush use, such as poor brushing technique and lack of compliance, thereby improving oral health[1,2]. Advances in the design and technology of power toothbrushes have led to numerous models of fundamentally distinct designs and modes of action with consequently different cleaning profiles[3]. One design based on the professional instruments used in dental prophylaxis is the Oral-B oscillating/rotating power toothbrush, which features a small, circular brush head for tooth-by-tooth cleaning and easier access to back teeth. Since its introduction, the Oral-B oscillating/rotating power toothbrush has evolved considerably with modifications in brush head design, brush head motion,

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Table 1 Development of the Oral-B range of power toothbrush

Oral-B power toothbrush	Angle of oscillation (°)	Oscillating frequency (Hz)	Pulsating frequency (Hz)
D5/D7	55	47	-
D9	55	63	-
D15[1]	55	63	170
D17[1]	45	63	340
PC 7000[1]	45	73	340

[1] Oscillating/rotating/pulsating toothbrushes known as the Oral-B ProfessionalCare Series.

frequency of movement, and operational features for the purpose of improving cleaning efficacy and gingival condition, and enhancing user acceptability (Tables 1 and 2). The original Oral-B Plaque Remover (the D5, latterly known as the D7) had an oscillating/rotating frequency of 47 Hz (2800 strokes per minute) and an angle of oscillation of 55°. An increase in operating frequency to 63 Hz enhanced the cleaning efficiency of the D9 model[4]. The next development, the D15, incorporated an additional pulsating action at a frequency of 170 Hz along the direction of the long axis of filaments giving three-dimensional or 3D brush head movement, an innovation developed to enhance penetration and plaque removal from approximal areas of the dentition[5]. In addition, advances in filament technology allowed replacement of the straight filaments in the D9 brush head with tufts of crimped filaments for less axial stiffness[6]. The D15 model was followed by the D17, in which the pulsating frequency was increased to 340 Hz and a pressure sensor is featured to stop the pulsations if too much pressure is applied. The brush head of the D17 is similar in size and configuration to that on the D15, but crimped filaments have been replaced by coextruded bifilaments to reduce axial stiffness, so that the filaments are softer and allow the interdental tips to have greater approximal penetration[7]. These bifilaments absorb moisture at different rates to allow greater flexibility and surface area exposure for cleaning. Both the D15 and D17 are included in the Oral-B ProfessionalCare Series and the most recent model to be developed in this range is the Oral-B ProfessionalCare 7000 (PC 7000), which has the same pulsating frequency of 340 Hz as the D17 but an increased oscillating frequency from 63 Hz to 73 Hz. In addition, the D15, D17 and PC 7000 models have a 2-minute timer to encourage recommended brushing time and the PC 7000 features a signal timed at 30-second intervals to indicate adequate cleaning for each quadrant of the dentition. The 2-speed control on the D17 and PC 7000 models provides users with a choice and an opportunity to use a lower speed while they become familiar with operation of the power toothbrush.

The development of the Oral-B power toothbrush has involved an extensive series of clinical studies, in which the oscillating/rotating action of the Oral-B has consistently shown to be highly effective in both

Table 2 Changes in brush head design and filament technology

Oral-B power toothbrush/ brush head	Brush head design[1]
D5/EB5, D7/EB7	Filament tufts arranged in 3 circular rings; the outer ring with filaments 8.3 mm long and 0.15 mm in diameter; inner two rings with filaments 7.6 mm long and 0.13 mm in diameter. Straight filaments.
D9/EB9	Three tufts of longer filaments (8.3 mm) on either side of the brush head in the outer ring and two inner rings of shorter filaments (7.2 mm). Straight filaments.
D15/EB15	Same configuration as D9/EB9, but with eight tufts of axially-soft crimped filaments in the inner field.
D17/EB17, PC 7000/EB17	Same configuration as D15/EB15, but with eight tufts of coextruded bifilaments in the inner field.

[1] All brush heads are 13.2 mm in diameter with end-rounded filament tufts and 0.15 mm diameter filaments.

plaque removal and gingivitis control[4,8,9]. Indeed, the Cochrane Collaboration conducted a recent independent systematic review across power toothbrushes of different modes of action and confirmed that oscillating/rotating toothbrushes have superior efficacy over manual toothbrushes in reducing both plaque and gingivitis, without compromising safety to oral tissues[10]. No other powered brush designs were found to be consistently superior to manual toothbrushes, including those with side-to-side, counter oscillation, circular or ultrasonic action. Given that the clinical experience with the oscillating/rotating D7 has been reviewed previously[8], the present review considers all the studies involved in the development of the Oral-B power toothbrushes with 3D action (oscillating/rotating/pulsating). Without excluding any study conducted on these toothbrushes, the present review focuses on efficacy and safety relative to earlier Oral-B models, manual toothbrushes, and other electric or power toothbrushes.

Laboratory and clinical development phases of a novel toothbrush

The early development phase of a novel toothbrush relies on the assessment of prototype models or design modifications in the laboratory before their clinical evaluation. Laboratory robot systems are totally controllable and eliminate many factors that potentially confound clinical studies such as variability in brushing technique, manual dexterity, brushing time and brushing force. Initially, the effect on cleaning efficacy of an additional pulsating action and modified brush head in the D15 model was investigated using a laboratory robot brushing system[11]. The highly reproducible digital imaging technique demonstrated that the oscillating/rotating/pulsating D15 was significantly more effective than the oscillating/rotating D9 in removing plaque substitute from all tooth surfaces, especially occlusal

surfaces and gumline sites[11]. Importantly, however, since it is not possible to represent precisely the conditions within the oral cavity in a model system, any improvements found *in-vitro* need to be substantiated in the clinical situation. A double-blind, randomised, crossover study conducted in 32 healthy subjects without dental training found the 3D action significantly improved plaque removal for the whole mouth and all approximal surfaces compared to the D9, in agreement with laboratory findings, and also observed no evidence of trauma to oral tissues[5]. The potential of the D9 and D15 models to cause gingival abrasion was investigated more closely in a single-use, examiner-blind, split-mouth design using a disclosing agent to highlight lesions that otherwise would be difficult to distinguish from normal gingivae[12]. No statistically significant differences between the two toothbrushes were found in the incidence of either small ($\leq$5 mm) or large (>5 mm) sites of abrasion and it was concluded both toothbrushes were safe to oral soft tissue under the conditions of the study.

Having established the enhanced plaque removal efficiency of adding a pulsating action to the clinically proven oscillating/rotating movement, the next phase in the development evaluated the safety and efficacy of the novel 3D brush head compared with manual toothbrushes and other established electric toothbrushes in a clinical setting. A series of well-controlled, randomised clinical studies of the D15 and D17 have evaluated oral health outcomes such as reduction in plaque, gingival inflammation, gingival bleeding, calculus and stain accumulation, as well as their safety with regard to soft and hard oral tissues in healthy subjects, patients receiving periodontal maintenance and in dental students[6,7,13-22]. To optimise data collection, clinical parameters were scored by the same examiner blinded to treatment allocation and usage sequence of the test products. Safety evaluation involved recording any adverse events reported and examination of the oral soft tissues (lips, tongue, gingivae, sublingual area, inner surfaces of the cheeks, mucobuccal folds, hard and soft palates, and the pharyngeal area) for colour, texture, abrasion and any irregularities. Since maintenance of oral health relies on compliance with a regular daily oral hygiene programme, several studies have investigated subject attitude to and preference for the D15 and D17 relative to other toothbrushes (manual and electric)[7,13,17,20,22].

The Oral-B oscillating/rotating/pulsating toothbrush (D15 and D17) versus a manual toothbrush

Several clinical studies have compared the D15 or D17 to a manual toothbrush for their relative safety and ability to remove plaque and improve gingival condition over a period of up to 6 months in healthy volunteers and subjects undergoing periodontal maintenance therapy[6,7,13-15]. Subjects were instructed to use the D15 or D17 toothbrush in accordance with instructions provided by the manufacturer and to use the power or manual toothbrush twice daily for two minutes.

Of these, two randomised, parallel-group, examiner-blind studies compared either the D15 or D17 models with a standard reference manual toothbrush in healthy subjects[6,7]. Plaque was scored using the Turesky et al. modification of the Quigley and Hein Plaque Index (TQHPI) at six surfaces of each tooth (the lingual and buccal surfaces, and the mesial and distal surfaces by both lingual and buccal aspects)[23,24]. Change in gingival condition was evaluated by assessment of both gingivitis (Löe & Silness gingival index; LSGI) and bleeding (LSGI scores of 2 or 3) over a 3-month period[25]. Before each clinical assessment, subjects abstained from oral hygiene for 12-18 hours to allow for overnight plaque formation. In both studies, plaque, gingivitis and bleeding improved significantly from baseline to month 3, but significantly greater improvements in mean whole mouth and approximal plaque and gingivitis were evident with the D15 and D17 toothbrushes ($p < 0.05$). After 3 months, reductions in whole mouth and approximal plaque, gingivitis and bleeding were greater with the D15 than the manual toothbrush by 7%, 8%, 4% and 9%, respectively (Tables 3 and 4)[6]. Corresponding reductions at 3 months with the D17 were greater by 7%, 6%, 6% and 19%, respectively, compared with the manual toothbrush (Tables 3 and 4)[7].

A further study compared the D15 with a manual toothbrush in their ability to improve gingival condition in subjects ($n = 35$) who had developed experimental gingivitis in the lower jaw after abstention of oral hygiene for 21 days, before commencing a 4-week treatment phase[13]. The split-mouth design allowed each subject to brush the right or left side of the mouth with either the D15 or the manual toothbrush as randomly assigned. Clinical assessments involved evaluation of plaque level by the TQHPI and the presence of gingivitis by bleeding on marginal probing. Both toothbrushes reduced plaque and bleeding during treatment, however, the D15 was significantly more effective than the manual toothbrush in reducing plaque and gingivitis, with greater reductions at all sites and approximal sites (Tables 3 and 4). Plaque levels and gingival bleeding were reduced significantly below baseline values at 4 weeks with the D15 only.

A three-period, examiner-blind, crossover study assessed plaque levels (TQHPI) and gingival bleeding on probing in 26 dental students randomly assigned to one of three treatment groups in which a different toothbrush (D9, D15 or a manual toothbrush) was used during a 2-week treatment period[14]. A recovery phase of one week preceded each treatment period, when no oral hygiene procedures were performed to eliminate carryover effects and to allow build-up of plaque deposits. During treatment, plaque levels scored by TQHPI and bleeding on probing decreased significantly with each of the toothbrushes, but no difference was found between the D9 and D15 versus the manual toothbrush. It was suggested that the recruitment of dental students may account for the

Table 3 Comparative clinical studies of the D15 or D17 versus a manual toothbrush on their relative effects on plaque removal

Study design	Duration	Group	Plaque reduction from baseline[1] (%)	
			Whole mouth / All sites measured	Approximal
Randomised, parallel-group, examiner-blind, healthy subjects[6]	3 months	D15 (n = 55)	15	15
		Manual (n = 50)	8	7
Randomised, parallel-group, examiner-blind, healthy subjects[7]	3 months	D17 (n = 52)	20	17
		Manual (n = 49)	13	11
Randomised, split-mouth, experimental gingivitis[13]	4 weeks	D15 (n = 35)	79	85 (vestibular) 63 (lingual)
		Manual (n = 35)	65	62 (vestibular) 49 (lingual)

[1] Plaque scored by Turesky et al. modification of the Quigley and Hein Plaque Index (TQHPI).

Table 4 Comparative clinical studies of the D15 or D17 versus a manual toothbrush on their relative effects on gingival condition

Study design	Duration	Group	Reduction from baseline[1] (%)	
			Gingivitis	Bleeding
Randomised, parallel-group, examiner-blind, healthy subjects[6]	3 months	D15 (n = 55)	16	65
		Manual (n = 50)	12	56
Randomised, parallel-group, examiner-blind, healthy subjects[7]	3 months	D17 (n = 52)	22	68
		Manual (n = 49)	16	49
Randomised, split-mouth, experimental gingivitis[13]	4 weeks	D15 (n = 35)	NA	75 (whole mouth)
		Manual (n = 35)	NA	57 (whole mouth)
		D15 (n = 35)	NA	81 (approximal vestibular)
		Manual (n = 35)	NA	64 (approximal vestibular)
		D15 (n = 35)	NA	71 (approximal lingual)
		Manual (n = 35)	NA	49 (approximal lingual)

[1] NA, not assessed.
Gingivitis scored by Löe & Silness Gingival Index (LSGI)[6,7].
Bleeding scored by Löe & Silness Gingival Index (LSGI scores of 2 or 3)[6,7] or bleeding on marginal probing[13].

lack of difference in efficacy between electric and manual toothbrushes in this study. Since dental students have greater expertise in performing optimal tooth cleaning procedures and a willingness to comply with instructions, smaller differences tend to occur in this study population during comparative studies of electric and manual toothbrushes[26]. It is also difficult to conduct gingivitis trials in a crossover design, due to the likelihood that gingival condition will improve during the first treatment period and not return to equivalent levels of gingivitis for the baseline of the second treatment period.

Another clinical study of the D15 versus a manual toothbrush compared their relative abilities to affect

clinical parameters of periodontal disease including plaque levels (TQHPI), gingivitis (LSGI), bleeding on probing, probing pocket depth and probing attachment levels[15]. In this 6-month, single-blind study, 48 periodontal maintenance subjects were randomly allocated either a manual ($n = 26$) or a D15 ($n = 22$) toothbrush, after which they received full mouth scaling and root planing. All subjects continued use of their current method of interdental cleaning. Mean pocket depth, mean plaque index and the percentage of sites exhibiting bleeding on probing significantly reduced from baseline at 3 and 6 months in both groups, and mean probing attachment level and mean gingival index were significantly reduced in the D15 group, but there were no significant differences between groups for any of the measured parameters.

Importantly, the D15 and D17 were also found to be as safe as a manual toothbrush[6,7,14,15]. Comparison of soft and hard oral tissue examinations at baseline and after 3 months of product use revealed no evidence of clinically significant soft or hard tissue abrasion associated with the use of either the power or manual toothbrush, which was further supported by the fact that gingival condition actually improved during the course of the studies[6,7]. In addition, improvement in probing attachment level in periodontal maintenance subjects, who had already demonstrated periodontal attachment loss, supports the safety and use of the D15 toothbrush in this clinical setting[15]. Closer scrutiny of any trauma to gingival tissues by assessment of the number and location of small (≤ 5 mm) and large (>5 mm) abrasions disclosed by staining, found no difference between the D9, D15 and manual toothbrush in the severity or extent of gingival trauma[14].

Overall, this series of clinical studies demonstrate that the oscillating/rotating/pulsating toothbrush offers advantages over manual toothbrushing in both plaque control and improvement of gingival condition, with no greater potential to cause gingival abrasion. Demonstration of improved oral health outcomes with a power toothbrush compared to a manual toothbrush under the controlled conditions of a clinical study is important, but only has practical relevance if users maintain long-term compliance in normal use. With regard to their attitude towards the D15 and D17, users found the power toothbrush to be effective[7] and preferred its use to a manual toothbrush[13]. A power toothbrush that is well-accepted by the user, as shown by D15 and D17, has the potential for enhanced long-term compliance.

The Oral-B oscillating/rotating/pulsating toothbrush (D15 and D17) versus other electric toothbrushes

Given that modern power toothbrushes vary considerably in their brush head design, filament type and arrangement, and mode and frequency of action, significant differences in their cleaning profiles can be expected. Comparative clinical trials of power toothbrushes provide essential evidence-based information to dental professionals as to the most effective models available. The safety and efficacy of the D15 and D17 models have been compared to several other power toothbrushes incorporating different concepts in design and/or operational technology.

A single-use, randomised, single-blind, crossover study in 74 healthy subjects compared the plaque removal efficacy of the D17 versus the Colgate® Actibrush™, a battery-operated device with an oscillating/rotating action[16]. Each subject used either brush on alternate days during a familiarisation period of approximately 2 weeks. After abstaining from oral hygiene for 23-25 hours, pre- and post-brushing plaque levels were assessed using a Proximal/Marginal Plaque Index[27]. Subjects brushed for 2 minutes without the use of a mirror to avoid biased cleaning and returned to repeat the procedures after a 2-week washout period, during which their normal method of oral hygiene was used. Both toothbrushes significantly reduced plaque levels ($p \leq 0.0001$), but the D17 was significantly more effective than the Actibrush for both the whole mouth ($p = 0.003$) and approximal sites ($p = 0.0002$). Plaque reductions from the whole mouth and approximal sites were 46.5% and 42.9%, respectively, for the D17 and 41.5% and 36.8%, respectively, for the Actibrush (Table 5). It is apparent from these findings that although toothbrushes may have some similar features, in this case a small round brush head and an oscillating action, other fundamental differences in oscillation frequency, oscillating angle and filament structure and configuration can result in meaningful differences in their clinical efficacy.

A single-blind, randomised, split-mouth study in 44 healthy subjects compared the plaque removal efficacy of the D15 and the Philips Sonicare® Plus™, a high-frequency power toothbrush with a side-to-side action that operates at a frequency of 260 Hz[17]. After a full mouth prophylaxis, subjects were instructed in the use of both toothbrushes and brushed their teeth twice daily on alternate days with each device over a 4-week practice period. Having abstained from oral hygiene for 48 hours, pre-brushing plaque levels were determined by the Rustogi et al. Modified Navy Plaque Index[28]. Subjects brushed two contralateral quadrants of the mouth with each toothbrush as randomly allocated and plaque was re-assessed. Plaque levels were significantly reduced by both brushes ($p = 0.001$), but significantly greater efficacy was found with the D15 for all comparisons (whole mouth, marginal and approximal surfaces for both buccal and lingual sites) ($p = 0.001$). Plaque reduction was notably greater with the D15 on approximal sites, where plaque removal was 87% versus 68% for the D15 and the Sonicare Plus, respectively (Table 5).

The plaque removal efficacy of the D15 and the Rowenta Dentasonic™ was compared in a randomised, examiner-blind, split-mouth study involving 82 healthy subjects[18]. The Dentasonic power toothbrush features a small, round brush head that vibrates together with the handle assembly at a frequency of 233 Hz and has a separate single tufted brush head intended for

Table 5 Comparative clinical studies of the D15 or D17 versus other power toothbrushes on their relative effects on plaque removal

Study design	Duration	Group	Plaque reduction from baseline[1] (%)		
			Whole mouth/ All sites measured	Marginal	Approximal
Randomised, examiner-blind, crossover, healthy subjects[16]	Single-use	D17 (n = 74)	46.5	55.2	42.9
		Colgate Actibrush (n = 74)	41.5	52.5	36.8
Randomised, split-mouth, single-blind, healthy subjects[17]	Single-use	D15 (n = 44)	67	43	87
		Sonicare Plus (n = 44)	50	23	68
				Buccal	Proximal
Randomised, split-mouth, single-blind, healthy subjects[18]	Single-use	D15 (n = 82)	36.6	45.1	33.1
		Dentasonic (n = 82)	26.1	32.3	23.2
Randomised, split-mouth, two separate studies of experimental gingivitis[19]	Experiment 1 4 weeks	D17 (n = 35)	53.0	NA	NA
		Sonicare (n = 35)	45.0	NA	NA
	Experiment 2 4 weeks	D17 (n = 32)	63.7	NA	NA
		Sensiflex 2000 (n = 32)	68.1	NA	NA
Randomised, split-mouth, experimental gingivitis[20]	4 weeks	D15 (n = 33)	52.5	NA	NA
		Sonicare Plus (n = 33)	42.2	NA	NA

[1] NA, not assessed.
Plaque scored by Proximal/Marginal Plaque Index[16], Rustogi et al. Modified Navy Plaque Index[17], and Turesky et al. modification of the Quigley and Hein Plaque Index (TQHPI)[18-20].

cleaning proximal tooth surfaces. All subjects received instruction in the use of both toothbrushes and used each brush twice daily for 2 minutes (for the Dentasonic this comprised 1 minute with the round brush and 1 minute with the single tufted brush, according to manufacturer's instructions) on alternate days during an 8-day acclimatisation period. After abstaining from oral hygiene for 48 hours, pre-brushing plaque was determined by the TQHPI at 6 sites per tooth (mesio-buccal, centro-buccal, disto-buccal, mesio-lingual, centro-lingual and disto-lingual). Subjects brushed two contralateral quadrants with each toothbrush as randomly allocated without dentifrice and post-brushing plaque was evaluated. Both toothbrushes significantly reduced plaque levels, but significantly greater reductions were observed with the D15 ($p < 0.005$). Plaque removal was 10%, 13% and 10% greater with the D15 at all sites, buccal and proximal surfaces, respectively (Table 5).

The comparative ability of the D17 versus the high-frequency Sonicare and the Philips Sensiflex 2000 to control plaque and reduce experimentally-induced gingivitis was investigated in two separate experiments each comprising three phases[19]. The familiarisation phase allowed subjects to become acquainted with the power toothbrushes and receive instruction in their use; the experimental gingivitis phase allowed development of gingivitis (>40% bleeding on marginal probing); and in the treatment phase, subjects brushed with their randomly assigned toothbrush according to a split-mouth design. The Philips Sensiflex 2000 features a round oscillating brush head with an active tip that operates independently of the main brush head at a frequency of 45-60 Hz. Plaque was assessed by TQHPI and gingivitis by bleeding on marginal probing. After 4 weeks of use, the D17 was significantly more effective than the Sonicare in plaque removal ($p = 0.006$) and resolution of gingival bleeding ($p < 0.0001$). At 4 weeks, plaque reduction was similar for both the D17 and Sensiflex 2000 toothbrushes ($p = 0.0995$), but bleeding reduction was significantly greater with the D17 ($p < 0.0001$). Mean percent reductions in plaque and gingival bleeding are shown in Tables 5 and 6.

The D15 and Sonicare Plus were also compared in their relative abilities to reduce plaque and improve the

Table 6 Comparative clinical studies of the D15 or D17 versus other power toothbrushes on their relative effects on gingival condition

Study design	Duration	Group	Reduction from baseline[1] (%)	
			Gingivitis	Bleeding
Randomised, split-mouth, two separate studies of experimental gingivitis[19]	Experiment 1 4 weeks	D17 (n = 35)	NA	31.3
		Sonicare (n = 35)	NA	23.6
	Experiment 2 4 weeks	D17 (n = 32)	NA	39.5
		Sensiflex 2000 (n = 32)	NA	29.1
Randomised, split-mouth, experimental gingivitis[20]	4 weeks	D15 (n = 33)	41.2	81.4
		Sonicare Plus (n = 33)	39.8	73.1

[1] NA, not assessed.
Gingivitis scored by Lobene modified Gingival Index[20]. Bleeding scored by bleeding on marginal probing[19,20].

gingival condition using a similar experimental gingivitis model[20]. Again, subjects abstained from oral hygiene for 21 days before the start of treatment in order to develop gingivitis. Thirty-three subjects participated in this randomised, split-mouth study where plaque and gingivitis were assessed initially, after 21 days of no oral hygiene, and after 2, 3 and 4 weeks of brushing twice daily on either side of the mouth with different toothbrushes. After 21 days without oral hygiene, mean mandibular plaque and gingivitis scores increased significantly for all subjects. Use of both electric toothbrushes during the treatment phase progressively reduced plaque and gingivitis scores at each successive examination ($p = 0.0001$), but significantly greater reductions in plaque at all visits and gingival bleeding at 4 weeks ($p < 0.05$) were evident with the D15 (Tables 5 and 6).

A further clinical study assessed the relative ability of the D17 and Sonicare Plus toothbrushes combined with a conventional dentifrice to control calculus and stain using a single-blind, crossover design in 81 healthy subjects[21]. A manual toothbrush used with a tartar control dentifrice served as a positive control. Calculus was assessed on the lingual surfaces of the six anterior mandibular teeth by the Volpe-Manhold Calculus Index[29] and extrinsic stain was assessed using the Lobene Stain Index[30] on buccal and labial (gingival region and body region) surfaces. Following a control period of 9 weeks of manual brush use with a conventional, non-abrasive dentifrice, each test brush was used for 9 weeks according to a randomised treatment sequence. All three brush regimens were safe as used in the study and significantly reduced the levels of calculus as compared to the control period. Reduction from baseline in the rate of calculus formation was greatest in the D17 group, followed by the manual brush with tartar control paste and the Sonicare (Table 7). Both the D17 and the manual brush with tartar control paste were significantly more effective than Sonicare ($p < 0.001$). The D17 was superior at controlling stain formation at the gingival margin compared with either Sonicare or the manual brush with tartar control paste ($p < 0.01$), with significant differences for D17 and the manual brush with tartar control paste from the Sonicare for the body of the tooth ($p \leq 0.05$).

A randomised, parallel-group, single-blind study compared the extrinsic stain-removing properties of the D15 and Sonicare Plus toothbrush in 67 healthy subjects over a period of 6 weeks[22]. All subjects were trained to use both devices and brushed twice daily with their assigned device for 2 minutes. The Lobene Stain Index was scored on the buccal surfaces of the anterior teeth and the labial surfaces, divided into the gingival region and the body of the tooth. At 6 weeks, oral hard and soft tissue examinations revealed no abrasion or damage in either group. Both brushes produced significant reductions from baseline in total stain score, stain area and intensity ($p < 0.001$), but group comparisons showed that the reductions were significantly greater for the D15 ($p < 0.001$). The percentage reductions in total stain score were greater with the D15 at all measured sites (Table 7) and for the gingival regions (73% versus 44%), body of the tooth (80% versus 64%), maxillary anterior (77% versus 53%) and mandibular anterior (75% versus 50%) surfaces. All differences in total stain scores between products were significant ($p < 0.05$), except for the body of the tooth ($p = 0.05$). Significantly more subjects in the D15 group expressed their satisfaction with the device than those in the Sonicare group (94% versus 81%, $p = 0.04$).

With regard to safety, there was no evidence of any clinically significant soft or hard oral tissue trauma associated with the use of any of the power toothbrushes during the course of the studies[16,17,20-22].

Although electric toothbrushes are generally known to enhance long-term compliance over manual brushing, not all electric toothbrushes are equally well accepted[3,8,31]. Three studies assessed subject preferences for and

Table 7 Comparative clinical studies of the D15 or D17 versus other power toothbrushes on their relative effects on stain and calculus

Study design	Duration	Group	Calculus	Stain		
				Total	Intensity	Area
			Reduction in formation (%)			
			Gingival region			
Randomised, examiner-blind, crossover, healthy subjects[21]	9 weeks	D17 (n = 81)	63	60	58	63
		Sonicare Plus (n = 81)	44	23	20	26
		Manual with tartar control dentifrice (n = 81)	60	39	35	43
				Body of the tooth		
		D17 (n = 81)		68	68	68
		Sonicare Plus (n = 81)		51	50	52
		Manual with tartar control dentifrice (n = 81)		67	68	65
				Stain removal from all sites (%)		
Randomised, examiner-blind, parallel-group, healthy subjects[22]	6 weeks	D15 (n = 34)	NA[1]	76	72	73
		Sonicare Plus (n = 33)	NA[1]	51	47	41

[1] NA not assessed.
Calculus scored on the lingual surfaces of the six anterior mandibular teeth by Volpe-Manhold Calculus Index[21].
Extrinsic stain scored by Lobene Stain Index[21,22].

attitudes towards the D15 and Sonicare power toothbrushes[17,20,22]. Overall satisfaction was found to be high for both products, but more subjects preferred the D15 mainly because of the size of its brush head and handle, which contributes to its ease of use and accessibility to clean all areas of the mouth. While these findings are clearly subjective, it is possible that user preference may result in better compliance with the D15 in the long term.

This series of clinical studies in the development programme indicate that the D15 and D17 were more effective than the comparator power toothbrushes in plaque removal and had greater potential to improve gingival health. Of particular relevance is the enhanced ability of the D15 and D17 to remove plaque from difficult-to-clean approximal sites, where gingival inflammation often develops. In addition, the 3D brush head action was found to be highly effective in controlling and reducing naturally occurring extrinsic stain and controlling the formation of calculus. Another critical aspect of power toothbrush design is subject motivation and given the D15 appears to be well-accepted, it may encourage long-term compliance under normal use.

Conclusions

The development of the Oral-B power toothbrush has involved an extensive research programme of both laboratory and clinical studies. *In-vitro* studies indicated that the addition of a pulsating action to the oscillating/rotating movement and advancements in filament technology and brush head design improved penetration of approximal areas and occlusal fissures, where plaque removal is most difficult. Although *in-vitro* models provide a useful development tool for the rapid assessment of design modifications, while controlling many factors that confound *in-vivo* studies, the relevance of their findings needs to be substantiated in the clinical situation by direct improvements in oral health. The unique, highly effective cleaning performance of the 3D action in the Oral-B ProfessionalCare Series is proven in both the laboratory and clinical situation. A series of well-controlled, randomised clinical studies conducted during their development has shown the superiority of the D15 and D17 models over a manual toothbrush and other power toothbrushes with various actions and designs in the improvement of oral health outcomes such as plaque removal efficacy (especially from approximal sites), reduction of gingival inflammation, and control of calculus and stain formation, establishing an evidence-based platform for the development of the most recent ProfessionalCare 7000. In addition, given that the oscillating/rotating/pulsating toothbrush was well-accepted by users, it is anticipated that its use may encourage long-term compliance with a regular daily oral hygiene programme.

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